## **NATIONAL INSTITUTES OF HEALTH**

## **Deputy Ethics Counselors/Ethics Coordinators**

Minutes – August 10, 2004 – 1:00 pm – Bldg 50, Room 1227

- **1. Announcement:** Holli Beckerman Jaffe, Gretchen Weaver, and Barb McGarey received the NIH Director's Award for setting up the NIH Ethics Advisory Committee (NEAC). Congratulations to them.
- 2. **NEAC Process:** The process for NEAC review of outside activities continues to be refined and a checklist for submitting activity requests is being finalized. To summarize:
  - The current process is that those received first will be processed first. Exceptions may be requested, e.g., due to short time frame.
  - Employees need to take responsibility for not engaging in the activity until it is approved, and to ask for a copy of the signed, approved request before starting to participate.
  - NEAC jurisdiction has not changed.
  - NIH is considering a policy that all awards will be reviewed by NEAC. No decision has been made.
  - Following NEAC review and signature by the NIH DEC, copies of the signed forms will be returned to the IC DEC/EC if the employee if part of the 'top 5' and the originals of the signed forms will be returned for other employees.

**ACTION:** Ms. Jaffe will distribute the 520 checklist as soon as it is finalized.

**ACTION:** Ms. Jaffe will ensure that her staff know when to return copies to the ICs or to return the original request forms.

- 3. **OGE Audit:** Nearly half of the 520s reviewed by OGE during their recent adit were not approved and the employee engaged in the activity without approval.
- **4. Work Flow in the NIH Ethics Office (NEO):** All documents should be submitted to Mattie Ward who tracks everything. Specialists are predominantly responsible for the following areas:

Elton Croy: Financial Disclosure Jon Donnelly: 520s

Diane Christensen: Official Duty Activities

- 5. Electronic Tracking and Conflicts Analysis: Dr. Zerhouni wants a database which can handle both work flow and permit conflicts analysis. EMIS will track workflow and assist the DEC and EC to identify potential conflicts. In addition, it will permit the ICs to see when an activity has been reviewed by NEAC and signed by the NIH DEC, and the outcome, even before the request is returned to the IC.
- **6. Acting Deputy Director, NIH Ethics Office:** Ms. Traci Melvin, long-time Ethics Coordinator at NIGMS is being detailed to the NEO beginning August 23<sup>rd</sup>. She will assist in the management of the office, especially looking at work flow processes and helping to streamline the office procedures.
- 7. Stock Holdings: See the questions on the agenda. NIH is in the process of requesting a change in the HHS Supplemental Standards of Ethical Conduct to prohibit certain employees from holding any financial interests in pharmaceutical and biotechnology companies, and to prohibit receipt of stock as compensation for outside activities. When finalized, there will be a implementation plan and grace period for affected employees. In addition, a 15-minute video is being prepared to inform employees of the changes, with a target availability of mid-September. Employees need to

understand that if/when the rules change, they may not be able to continue certain outside activities nor hold certain financial interests. Additional campus-wide input is not being sought since more than 300 employees talked to the Blue Ribbon Panel on Conflict of Interest Policies. The Blue Ribbon Panel considered prohibiting stock as compensation but chose not to make that a recommendation. Dr. Zerhouni has chosen to do so at this time. There is no final proposal at this time. Recommendations will be modeled after the FDA prohibitions on stock ownership. NIH is still trying to determine/define what would be prohibited without using general terms like "pharmaceutical" or "biotech" company. Questions raised by the ethics community included:

- Has there been consideration of the impact on loss of current employees or recruitment difficulties?
- What about giving stocks to parents? Technically, it could be done as long as the employee did not expect to get it back.
- What is the approval process/time frame? The NIH portion would be added to 5 CFR 5501, a separate section for NIH employees, just like there are sections specific to FDA and IHS employees.
- 8. Official Duty Requests: Draft guidance on when employees must request approval, the form of the approval, and other relevant guidelines will be distributed soon. Current policy remains in place for travel-related activities:
  - For local travel, no ODA memo is necessary.
  - For other travel, ODA memo must be signed prior to travel orders being signed.
  - No ODA memo is necessary for ODA travel involving Federal entities.
- 9. NIH 2657 does DEC need to sign Part D? Since the DEC signs the HHS 520, and the NIH 2657 is an attachment to the HHS 520, the DEC does not also need to sign Part D of the NIH 2657.
- 10. Update on Ethics Working Groups: The purpose of the groups is to help with policy and operational issues for the entire NIH ethics community, to conceptualize and draft documents, etc., for review and concurrence by the DECs and ECs prior to submission to the NIH DEC and Director for comments and implementation. Currently there are four groups. The process for the next step is for a volunteer from each group to schedule the initial meeting where the WG will designate the Facilitator and brainstorm priority issues for review and discussion by the other DECs and ECs. Facilitators will prepare a summary of the issues and tasks. For the first round of summaries, Facilitators will send the document to Ms. Pohl and Ms. Stroh, who will re-distribute the summary documents to other DECs and ECs. After the initial round, WG Facilitators will distribute information directly to the NIH ethics community as it is ready for review and feedback.

Working Groups (WG) - Facilitators (interim):

Database (e.g., EMIS)

Financial Disclosure

Training

Official & Outside Activities

Jeanellen Kallevang, NICHD

Karen DeLeon, NHGRI

Elton Croy, OD/NEO

Nadgy Roey, NLM

Followup: Information on the Working Groups and membership is posted on the NIH Ethics Program web site, on the 'meetings' page. Http://ethics.od.nih.gov/meeting.htm

**ACTION:** Facilitators will send summary document to Ms. Pohl and Ms. Stroh by August 24<sup>th</sup>, who will then redistribute the documents without change to the DECs and ECs. Additional summaries will be submitted for re-distribution by September 10th.

**11. HHS DEC Workshop:** Though tentatively scheduled for September 14<sup>th</sup>, it appears that the DEC Workshop will not be held until the spring of 2005.

- **12.** Equivalency Determination for Additional 278 Filers: The equivalency determination letter from OGE is expected by the end of August 2004. The NIH Ethics Office and OGC staff will provide training to 278 filers to complete the SF 278 electronically. They will also help train 450 filers as requested by the ICs.
  - **ACTION:** Ethics staff were encouraged to become familiar with the electronic filing format for the SF 278 found on the OGE website, to download, install, and practice using the software so they can assist their employees and encourage its use.

Reminder: Employees who already file the SF 278 because they are SES or in a position which requires filing the SF 278 will still be required to file, even if their name or position are not mentioned on the equivalency determination letter indicating new filers.

- **13. Congressional Investigation:** The NIH continues to receive calls from Congress about why some activities were removed from the spreadsheets.
- **14. Election Year Activities:** Attendees were reminded that the OGC has responsibility for answering questions regarding political activities. In addition, staff can check the Office of Special Counsel web site for information and to submit questions (http://www.osc.gov).
- 15. Spousal Information on an OGE 450: If an employee is unable to obtain appropriate information from a spouse to include on his/her OGE 450, document that fact. Employees are not required to report the spousal holdings if they are officially separated or divorcing. Living in separate areas due to jobs does not constitute being officially 'separated.' This is detailed in the Instructions accompanying the OGE 450 form: Section G, Item #3:

"....Information about your spouse is not required in the case of divorce, permanent separation, or temporary separation with the intention of terminating the marriage or permanently separating..."

Next Regularly Scheduled DEC/EC Meeting: Tuesday, September 14, 2004; 1:00 pm

Natcher Building, Room F1/F2

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